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I acknowledge the duty to disclose information that is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (reprinted below):

# § 1.56 Duty to disclose information material to patentability.

- A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of cand and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of any claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
  - (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
  - (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim
  - (2) It refutes, or is inconsistent with, a position the applicant takes in:
    - (i) Opposing an argument of unpatentability relied on by the Office, or
    - (ii) Asserting an argument of patentability.

A prima facic case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
  - (1) Each inventor named in the application:
  - (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.
- (e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Albrecht, John W.	Reg. No. 40,481	Leon, Andrew J.	Reg. No. 46,869
Ali, M. Jeffer	Reg. No. 46,359	Leonard, Christopher J.	Reg. No. 41,940
Anderson, Gregg I.	Reg. No. 28,828	Liepa, Mara E.	Reg. No. 40,066
Batzli, Brian H.	Reg. No. 32,960	Lindquist, Timothy A.	Reg. No. 40,701
Beard, John L.	Reg. No. 27,612	Lycke, Lawrence E.	Reg. No. 38,540
Berns, John M.	Reg. No. 43,496	Mayfield, Denise L.	Reg. No. 33,732
Black, Bruce E.	Reg. No. 41,622	McDonald, Daniel W.	Reg. No. 32,044
Branch, John W.	Reg. No. 41,633	McIntyre, Jr., William F.	Reg. No. 44,921
Bremer, Dennis C.	Reg. No. 40,528	Mitchem, M. Todd	Reg. No. 40,731
Bruess, Steven C.	Reg. No. 34,130	Mueller, Douglas P.	Reg No. 30,300
Byrne, Linda M.	Reg. No. 32,404	Nichols, A. Shane	Reg. No. 43,836
Campbell, Keith	Reg. No.P-46,597	Pauly, Daniel M.	Reg. No. 40,123
Carlson, Alan G.	Reg. No. 25,959	Phillips, Bryan K.	Reg. No. P-46,990
Caspers, Philip P.	Reg. No. 33,227	Phillips, John B.	Reg. No. 37,206
Chiapetta, James R.	Reg. No. 39,634	Prendergast, Paul	Reg. No. 46,068
Clifford, John A.	Reg. No. 30,247	Pytel, Melissa J.	Reg. No. 41,512
Coldren, Richard J	Reg. No 44,084	Qualey, Terry	Reg. No. 25,148
Daignault, Ronald A.	Reg. No. 25,968	Reich, John C.	Reg. No. 37,703
Daley, Dennis R.	Reg. No. 34,994	Reiland, Earl D.	Reg. No. 25,767
Dalglish, Leslie E.	Reg. No. 40,579	Samuels, Lisa A.	Reg. No. 43,080
Daulton, Julie R.	Reg. No. 36,414	Schmaltz, David G.	Reg. No. 39,828
DeVries Smith, Katherine M.	Reg. No. 42,157	Schuman, Mark D.	Reg. No. 31,197
DiPietro, Mark J.	Reg. No. 28,707	Schumann, Michael D.	Reg. No. 30,422
Edell Robert T.	Reg. No. 20,187	Scull, Timothy B.	Reg. No. 42,137
Epp Ryan, Sandra	Reg. No. 39,667	Sebald, Gregory A.	Reg. No. 33,280
Glance, Robert J.	Reg. No. 40,620	Skoog, Mark T.	Reg. No. 40,178
Goggin, Matthew J.	Reg. No. 44,125	Spellman, Steven J.	Reg. No. 45,124
Golla, Charles E.	Reg. No. 26,896	Stoll-DeBell, Kirstin L.	Reg. No. 43,164
Gorman, Alan G.	Reg. No. 38,472	Sumner, John P.	Reg. No. 29,114
Gould, John D.	Reg. No. 18,223	Swenson, Erik G.	Reg. No. 45,147
Gregson, Richard	Reg. No. 41,804	Tellekson, David K.	Reg. No. 32,314
Gresens, John J.	Reg. No. 33,112	Trembath, Jon R.	Reg. No. 38,344
Harrier, Samuel A.	. Reg. No. 46,754	Tuchman, Ido	Reg. No. 45,924
Hamre, Curtis B.	Reg. No. 29,165	Tunheim, Marcia A	Reg. No. 42,189
Harrison, Kevin C.	Reg. No.P-46,759	Underhill, Albert L.	Reg. No. 27,403
Hertzberg, Brett A.	Reg. No. 42,660	Vandenburgh, J. Derek	Reg. No. 32,179
Hillson, Randall A.	Reg. No. 31,838	Wahl, John R.	Reg. No. 33,044
Holzer, Jr., Richard J.	Reg. No. 42,668	Weaver, Karrie G.	Reg. No. 43,245
Johnston, Scott W.	Reg. No. 39,721	Welter, Paul A.	Reg. No. 20,890
Kadievitch, Natalie D.	Reg. No. 34,196	Whipps, Brian	Reg. No. 43,261
Karjeker, Shaukat	Reg. No. 34,049	Whitaker, John E.	Reg. No. 42,222
Kastelic, Joseph M.	Reg. No. 37,160	Wickhem, J. Scot	Reg. No. 41,376
Kettelberger, Denise	Reg. No. 33,924	Williams, Douglas J.	Reg. No. 27,054
Keys, Jeramie J.	Reg. No. 42,724	Withers, James D.	Reg. No. 40,376
Knearl, Homer L.	Reg. No. 21,197	Witt, Jonelle	Reg. No. 41,980
Kowalchyk, Alan W.	Reg. No. 31,535	Wu, Tong	Reg. No. 43,361
Kowalchyk, Katherine M.	Reg. No. 36,848	Xu, Min S.	Reg. No. 39,536
Lacy, Paul E.	Reg. No. 38,946	Zeuli, Anthony R.	Reg. No. 45,255
Larson, James A.	Reg. No. 40,443	-	

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

Please direct all correspondence in this case to Merchant & Gould P.C. at the address indicated below:

Merchant & Gould P.C. P.O. Box 2903 Minneapolis, MN 55402-0903



6123329081

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application or any patent issued thereon.

2	Full Name Of Inventor	The state of the s		Second Given Name
0	Residence & Citizenship	The state of the s		Country of Citizenship KOREA
1	Mailing Address	Address  Main Bidg, STE-512, Youngnam University Col. Med., 317-1, Daemyung-dong, Nam-gu	City Daegu-shi	State & Zip Code/Country KOREA
Sign	ature of Inventor 1	101: WZ		Date: January 22, 200/
<u>.</u>	Full Name Of Inventor	Family Name KIM	First Given Name Sung-Kwang	Second Given Name
· ·	Residence & Citizenship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
.9==			City Daegu-shí	State & Zip Code/Country KOREA
ign	sture of Inventor 2			Date: January 12, 200
	1	Family Name LEE	First Given Name Jong-Scok	Second Given Name
	Residence & Citizenship	City Desgu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
	1	Address Main Bldg. STE 512, Youngnam University Col. Med., 317-1, Daemyung-dong, Nam-gu	City Daegu-shi	State & Zip Code/Country KOREA
	ture of Inventor 2	0] 공석		Date: JANUARY 22, 200
	Full Name Of Inventor	Family Name LEE	First Given Name Jai-Youl	Second Given Name
	Residence & Citizonship	City Daegu-shi	State or Foreign Country KOREA	Country of Citizenship KOREA
ı	Mailing Address	Address 1370, Sankcok-dong, Book-gu	City Daegu-shi	State & Zlp Code/Country KOREA
ilgn	sture of Inventor 2	04: 61 24 ah		Date:  January 22, 200

# **SMALL BUSINESS**

# VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f)) - SMALL BUSINESS CONCERN

I here	by declare	that I am	A			
	a) 🔲		r.of the small business c	ancern identified had	lave	
	b) 🗍	an officia	if of the small business of	oncem identifica per	iuw. Io act on behali	f of the concern identified below:
	.,		d Jindii Casinoss C	oncem empowered i	o act on benat	tot the concern identified below:
		NAME	OF CONCERN:	BIOGENIA CO., I	TD	
			SS OF CONCERN:	Owner Venture Bl		
		,		1661, Bongchun-d	ug. Sic 407	
				Seoul, KOREA	ong, Kwanack	-gu
			•	Jeoui, ROREA		
I herel	v declare	that the abo	ove identified small husi	nece concern qualifi	an na n amali k	usiness concern as defined in
13 C.F	R. 121.80	11-805. and	reproduced in 37 C F P	1 O(d) for purpose	es as a sinali o	duced fees under Section 41(a) and (b) of Fitle
35. Un	ited States	Code in t	hat the number of emplo	weer of the concern	s of paying rec	auced lees under Section 41(a) and (b) of little
For bu	rnoses of t	his stateme	ent (1) the number of en	ryces of the concern,	including thos	se of its affiliates, does not exceed 500 persons.
concer	n of the ne	ersons emn	loved on a full-time nar	t-time or termorous	hasia duning sa	the average over the previous fiscal year of the
concer	ns are affil	listes of es	rh òthur when either die	continue of temporary	Dasis during ea	ach of the pay periods of the fiscal year, and (2)
third n	arty or mar	ties contro	is or has the power to co	ectly of indirectly, o	ne concern coi	ntrols or has the power to control the other, or a
	unity of par	mes county	is or mas tric power to co	muoi oom.		
l hereb	v declare t	that rights :	mder contract or law ha	vo boos conversed to		ith the small business concern identified above
with re	gard to the	invention	antitlat A haltites	Ae occii collacăcă io	and remain wi	in the small business concern identified above
AMPI	FICATIO	WIED 13	E12 DEDEATED CEAL	ON DETECTING N	ATCOBACTE	RIUM TUBERCULOSIS BY PCR
SPAK	I FF IAI	-YOUL de	coribad in	ENCE by inventor	S) LEE, TAE-	YOON; KIM, SUNG-KWANG; LEE, JONG-
	, LLL, JAI	- i OOD uç	scribed (i)			
122	a) 🔲	dia concifi	cation filed herewith.			
		nravisions	al application serial no _	Clad		
1912	0) 図	provisione	sional application serial	, med	C1. 3	
		natent no	, issued,	no	, Itled	Philosoph same physical Pater Space Company Company Company Company
	ريسا (۵	patent no.	, issued,			
f the r	ights held l	by the abov	e-identified small busin	ess concern are not	evalucius sach	n individual, concern or organization having
ights t	o the inver	ition is list	ed below* and no rights	to the invention are	bald by any no	erson, other than the inventor, who could not
malify	as an inde	nendent in	ventor under 27 C F D	to the invention are	neid by any pe	uld not qualify as a small business concern
ınder 3	7 C F R I	9(d) or å i	conprofit organization u	nder 27 CED 10/a	CIN WILICH WO	aid not quality as a small business concern
IJ				11401 37 C.1 .1C. 1.5(C)	<i>).</i>	
NAME:						
4DDRE	SS:	***************************************	<del></del>	<del></del>		
	a) INDIV	/IDUAL	b) SMALL BUSIN	ESS CONCERN	c)   N	ONPROFIT ORGANIZATION
VAME ADDRE	ee. ———		<del></del>		<del></del>	
MAINE	.) CINDIV	IDUAL.	b) LI SMALL BUSIN	FCC PANACEDM	-VII N	ONPROFIT ORGANIZATION
			5/ <u>21</u> 3/18-02 50,311	DJS CONCERN	0,53 (4)	ONFROFII ORGANIZATION
ackno	wledge the	duty to fil	e, in this application or	patent, notification o	f any change i	n status resulting in loss of entitlement to small
entity s	tatus prior	to paying,	or at the time of paying,	the earliest of the is	sue fee or any	maintenance fee due after the date on which
tatus a	s a small e	ntity is no	longer appropriate. (37	C.F.R. 1.27(g)(2))	•	
hereby	declare the	nat all state	ments made herein of m	y own knowledge ar	e true and that	all statements made on information and belief
re beli	eved to be	true; and f	urther that these stateme	nts were made with	the knowledge	that willful false statements and the like so
nade ai	e punishal	ble by fine	or imprisonment, or bot	h under Section 100	l of Title 18 of	f the United States Code, and that such willful
alse sta	itements m	ay jeopard	ize the validity of the ar	plication, any patent	t issuing there	of, or any patent to which this verified
lateme	nt is direct	ed.		•	C	, , , , , , , , , , , , , , , , , , , ,
NAME						
TITLE:						
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IGNA	TURE:		J112		Date:	MM1/11 1-2:2001
			VVV			

MERCHANT & GOULD P.C.

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M&G: 12777.8US01

#### **INDEPENDENT INVENTOR(S)**

# VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C F.R. 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

	a) [ b) [	the specifica	tion filed herewith.  pplication serial no, f	ilad	
	6) [2	non-movisio	nal application serial no.	, filed	
	d) [	] patent no.	, issued		· · · · · · · · · · · · · · · · · · ·
	convey or lice under 37 C.F.	onse, any rights R. 1.9(c) if that	in the invention to any person person has made the invention	under no obligation under con who could not be classified a in, or to any concern which we anization under 37 C.F.R. 1.9(	s an independent inventor ould not qualify as a small
	Each person, ounder contract	concern or orga t or law to assig	nization to which I have assign, grant, convey, or license a	ned, granted, conveyed, or lice ny rights in the invention is list	ensed or am under obligation ted below:
		25° [7] 20	such person, concern, or organ	nization	
			sons, concerns or organization		
		y was pure	, 42.10		
į	NAME	BIOGENIA (	CO., LTD.,		**************************************
	ADDRESS	Owner:Ventu	re Bldg. Ste 409, 1661, Bong	chun-dong, Kwanack-gu, Seor	ul, KOREA
=		a) 🔲 INDIVI	· <del>-</del>	SINESS CONCERN c) NO	PROFIT ORGANIZATION
	NAME	LEE, Tae-Yo	ion	ty Col. Med., 317-1, Daemyun	a dong Nam cu Daggu
1	ADDRESS	shi, KOREA		ty Col. Med., 317-1, Daemyun	g-dong, Nam-gu, Dacgu-
į.		a) M INDIVID	UAL b) SMALL BUST	NESS CONCERN c)   NON	PROFIT ORGANIZATION
8) (2) INDIVIDUAL B) [1] SMALL BUSINESS CONCERN C) [1] NON ROTH CROSS CONCERN					
		•		•	
1	I acknowledge	e the duty to file	e, in this application or patent	, notification of any change in	status resulting in loss of
and Amp	entitlement to	small entity sta	e, in this application or patent	, notification of any change in	status resulting in loss of he issue fee or any
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	entitlement to maintenance i I hereby decla information as willful false st Title 18 of the any patent issu NAME OF IN	small entity state for that all state and belief are be tatements and the United States uing thereof, or	e, in this application or patent tus prior to paying, or at the date on which status as a sments made herein of my own lieved to be true; and further the like so made are punishable Code, and that such willful far any patent to which this vering NAME OF INVENTOR	notification of any change in time of paying, the earliest of tall entity is no longer appropriate knowledge are true and that a that these statements were made by fine or imprisonment, or lise statements may jeopardize fied statement is directed.  LEE, Jong-Seok  NAME OF INVENTOR	status resulting in loss of he issue fee or any ate. (37 C.F.R. 1.27(g)(2)) will statements made on the with the knowledge that both under Section 1001 of the validity of the application,  LEE, Jai-Youl  NAME OF INVENTOR  O 27 Ch  Signature of Inventor
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23552 PATENT TRADEMARK OFFICE

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### **INDEPENDENT INVENTOR(S)**

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 C.F.R. 1.9(f)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 C.F.R 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled A METHOD FOR DETECTING MYCOBACTERIUM TUBERCULOSIS BY PCR AMPLIFICATION REP 13E12 REPEATED SEQUENCE described in

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	b) [ c) 🔀	provisional non-provisional	ation filed herewith. application serial no, fonal application serial no,, issued	iled, filed, filed			
	convey or licer under 37 C.F.I	t assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, license, any rights in the invention to any person who could not be classified as an independent inventor C.F.R. 1.9(c) if that person has made the invention, or to any concern which would not qualify as a small concern under 37 C.F.R. 1.9(d) or a nonprofit organization under 37 C.F.R. 1.9(e).					
		ach person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under obligation ander contract or law to assign, grant, convey, or license any rights in the invention is listed below:					
			such person, concern, or organ sons, concerns or organization				
	NAME	BIOGENIA	CO LTD				
	ADDRESS	Owner Vent	ire Bldg. Ste 409, 1661, Bong	chun-dong, Kwanack-gu, Seou SINESS CONCERN c) NON			
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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. 1.27(g)(2))							
	I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereof, or any patent to which this verified statement is directed.						
	LEE, Tae-You			A CONTRACTOR OF THE PROPERTY O	ALL OF OF DIVIDITION		
	NAME OF IN	VENTOR	NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR		
	Signature of Ir	ventor	Signature of Inventor	Signature of Inventor	Signature of Inventor		
-	Date	144mi 22	Date	Date	Date		
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